Exhibit "1"

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE NO. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

ALFREDA LEE, et al., V. ETHICON, INC., et al.
CIVIL ACTION NO. 2:12-cv-01013

SUSAN THAMAN V. ETHICON, INC., et al.,
CIVIL ACTION NO. 2:12-cv-00279

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DEPOSITION OF
JOHN R. MIKLOS, MD

April 8, 2016
10:52 a.m.
3575 Piedmont Road, NE
Atlanta, Georgia

Heather Brown, RPR
CCR-4759-4284-5258-1376
~~~~~~

APPEARANCES OF COUNSEL

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Deposition of John Miklos, M.D.
April 8, 2016

JOHN R. MIKLOS, M.D.,
having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. SNELL:

Q. Good morning, Dr. Miklos, my name is Burt Snell. We met off the record a little while ago. I'm here to take your deposition particularly regarding your TVT-Secur expert report and the multi-district Ethicon litigation. You understand that?

A. Yes.

Q. Can you just tell us your full name and where you're current business address is, please, doctor?

A. Yes. My name is John Robert Miklos. My -- I have an office here in Atlanta at 3400 Old Milton Parkway, Suite C330, Alpharetta, Georgia 30005, and I have an office also in Beverly Hills at 9201 Sunset -- West Sunset Boulevard, and that's West Hollywood or Beverly Hills and that's suite 402. And I have a new office in Dubai but I don't know the address.

Q. Okay. I'm going to hand you what has been marked as Exhibit No. 1. I'll represent that that is the notice to your deposition, and my simple question is have you seen this

document before?

(Whereupon Exhibit Miklos 1 was marked for identification.)

A. Yes.

Q. Have you brought any materials here with you in response to the document request that's attached to the deposition exhibit?

A. Yes. Actually Jim and I spoke about this document -- I saw this on Wednesday -- and basically, Jim has coalesced everything and brought everything with him.

Q. Right. So you have a couple of binders here, there's a CD down there. Counsel, is that yours or is that the doctor's?

MR. MATTHEWS: I'll just tell you what we've got.

MR. SNELL: Okay. That's fine.

MR. MATTHEWS: The binders are his report and the documents that represent the footnotes in his report.

MR. SNELL: Okay.

MR. MATTHEWS: The CD is the same thing. So that you can have it, if you want it.

MR. SNELL: Okay.

MR. MATTHEWS: Do you want it?

MR. SNELL: Yeah. I think I'll mark that.

MR. MATTHEWS: The -- his file, to the extent

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that we hadn't objected to it, and actually, I think this is everything that is on this thumb drive.

MR. SNELL: Okay.

MR. MATTHEWS: So this would include everything that he was sent to review and reviewed that's listed on his exhibit list. That's yours, too.

MR. SNELL: Okay. Perfect.

MR. MATTHEWS: And I don't remember what else is on -- there are invoices, right?

MR. SNELL: Yeah, there was a request for invoices if he's generated those at this point.

MR. MATTHEWS: There's the invoices to this point I think.

MR. SNELL: Okay.

MR. MATTHEWS: Let's see. The rest of this I don't think is responsive in this stack here.

MR. SNELL: Okay.

MR. MATTHEWS: So that's it.

MR. SNELL: Perfect.

Q. (By Mr. Snell) So, Doctor, thank you for bringing those materials, as well.

I'm handing you Exhibit No. 2. This is a formality, I know you have a copy of your expert report there in your binder. Can you just confirm for us that Exhibit 2 is a copy of your export report on the TVT-Secur?

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(Whereupon Exhibit Miklos 2 was marked for identification.)

A. Yes.

Q. What I did is I took apart the package the lawyers filed that included the report, the CD, materials list, just so we can separately mark them.

Exhibit No. 3 to your deposition appears to be your curriculum vitae. Can you confirm if that's correct?

(Whereupon Exhibit Miklos 3 was marked for identification.)

A. Yes.

Q. Is that current or current as of a certain date?

A. Yes. It is current as of December 2015.

Q. Since December of 2015, have you drafted or prepared an updated CV?

A. I -- we haven't updated the CV since that time. If it is, it would be minor. But there's -- my career continues to -- there's things every month or so that we have to add to it, so it hasn't been updated that I'm aware of.

Q. Can you think of anything significant that you've done, written, published, that would be reflected on the updated CV that pertains to TVT-Secur or your opinions in this case?

A. Yeah. In particular, even though they're written in my expert report, that we created three abstracts for the

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International Urogynecological association meeting on mesh removal.

Q. I'm familiar with those.

A. We've actually taken -- the process is taking each abstract and creating a paper out of it. So Abstract No. 1 is now accepted for publication in the International Urogyne Journal and it's on MEDLINE, but it's not formally published yet, so pending publication. And then two other papers, the next two, one has been submitted -- or they're both getting ready to be submitted for publication.

Q. Okay.

A. That's the one thing. The next thing is that I did a mini fellowship in chronic pelvic pain and am going back to do another 5 to 6 weeks of chronic pelvic pain in Zurich, Switzerland --

Q. Okay.

A. -- and this particularly relates to the concept of patients that are permanently damaged due to pelvic surgery.

Q. So if I understand you correctly -- I am familiar with the abstracts published on mesh removal and mesh complications, but I've only seen them in abstract form. Am I correct that those have not been peer reviewed and published externally by the International Urogyne Journal, so that I could pull down a copy off PubMed if I wanted it?

A. On PubMed, the only thing that you would see -- I

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don't -- the abstract is up, but unless you purchased it from International Journal, it should be available.

Q. Okay.

A. But we can get you a copy. I didn't bring it with us.

Q. Yeah, I'm not asking for a copy from you.

A. Okay.

Q. I was just -- because I tried to get a hold of it and look at it but, at least according to the search I did, I could not get access to it. That's neither here nor there.

A. Okay.

Q. I won't bother your time with that.

The mini fellowship in pelvic pain that you did, was that in Switzerland as well --

A. Yeah.

Q. -- or somewhere here in the States?

A. No. It's in Zurich.

Q. How long was that mini fellowship?

A. Well, I've already spent basically two weeks, but I'm going back now for another six weeks, maybe ten weeks, so it ends up being two to three months total.

Q. I'm pretty familiar with your background. I know your education, training, I'm not going to go through any of that stuff but, at least as I have seen, it looks like you were one of the early surgeons in this country, at least, who began

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doing, what I will call more minimally invasive procedures, beginning in the 90s with regard to laparoscopic procedures; is that true?

A. Yes. I would say that's true.

Q. Can you tell me -- just give me an overview of what your current practice is like. Are you straight female pelvic medicine or are you doing other things like, you know, laparoscopic procedures, vaginal rejuvenation, whatever it is?

A. Yes. Well, I'm a urological gynecologist. Which -- and I'm board certified in female pelvic medicine and reconstructive surgery. I did a two-year fellowship in that, so that is my specialty, but I also did two years of minimally invasive -- same concept -- reconstructive pelvic surgery. On top of that, I spent a couple months learning cosmetic vaginal surgery.

So my practice is dedicated to the reconstruction of female pelvises. Dedicated to women, only urogynecologic and gynecologic cosmetic surgical procedures. So it's strictly dedicated to that, and it's been that way since 1995. No obstetrics, no routine OB/GYN, no pap smears -- maybe one or two pap smears a year.

Most patients are either referred to me -- they find me, and they're not permanent patients. They come usually for an evaluation, diagnostic, treatment, if necessary, and then hopefully they move on.

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Q. Do you still do a fair amount of laparoscopic procedures?

A. Absolutely.

Q. Would it be fair to say that the most influential variable in outcomes is the skill set of the surgeon?

A. Repeat the question, please.

Q. Sure. Would it be fair to say that the most influential variable affecting patient outcomes following surgery is the skill set of the surgeon?

A. I've never looked at that scientifically, but I believe that the skill of the surgeon plays one of the most important roles, yes.

Q. For instance, I know you are well-published and have a good reputation -- a very good reputation in laparoscopic surgical procedures. There are other surgeons who have access to those same laparoscopic trocars, you know OR set up, et cetera, but who do not have results as good as yours as published. What would you attribute that to, if anything, beyond the skill set of the surgeon?

A. Oh, multiple things. It's obviously education, training, commonsense, pragmatism, logic doing surgery. I can even equate it back to just how I was raised. But that being said, it also requires that -- well, let me put it this way: I have the great fortune of operating all over the world, and having the appropriate equipment is extremely important, too.

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So it's a combination of things; skills, training, education, knowledge, and good equipment, and the appropriate patients, too. It's a lot -- you'll have better success usually in patients that are maybe healthier, not -- have a lower body mass index --

Q. Right.

A. -- and not as many previous surgeries.

Q. Okay. Can you tell, me what's your current treatment modalities you use for the surgical treatment of female stress urinary incontinence?

A. Sure. If I'm going to isolate it a little bit, because it changes and it is a dynamic situation, currently I use primarily three different modalities: Laparoscopic Burch; Johnson & Johnson Gynecare TVT Exact, or the retropubic sling; and a minimally invasive single-incision sling on occasion -- which is made by Coloplast -- it's called an Altis, A-l-t-i-s. And the general makeup has changed dramatically over the last three years. Dr. Moore, my partner, has recently gone through our cases with one of our research assistants and found that we were approximately 75 to 80 percent synthetic slings three years ago and currently, last year, we were at 77 percent Laparoscopic Burch again.

Q. Okay. The Coloplast Altis, I'm not familiar with that sling. I know you had done, in the past, the MINI ARC, true?

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A. Yes, MINI ARC.

Q. Coloplast Altis, is that a polypropylene sling or is it made of some other material?

A. Polypropylene.

Q. Is that a Type One macroporous polypropylene mesh, monofilament?

A. Yes.

Q. When you do your Lap Burch, do you use permanent sutures?

A. Yes.

Q. What type?

A. Cortex.

Q. How many?

A. I do a Tanaga Modification, and that's four sutures.

Q. The Coloplast Altis, of those three procedures, is that the one you do the least by volume?

A. Yes.

Q. Are there certain patient cohorts or categories you reserve that Mini-Sling for or stay away from? Such that, obviously I'm not going to do that on a recurrent patient or an ISD patient?

A. Very good. I tend to shy away if they have -- the word Intrinsic Sphincter Deficiency or ISD, depending on who you talked to, encompasses -- it can encompass every patient. Urologists will tell you every patient has some ISD, it's a

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matter of how much they have. And, right, the more ISD they have, the more likely I'm going to go to the retropubic sling. If they've had multiple surgical procedures, the more likely I'm going to use a retropubic TVT Gynecare sling. If they've had a frozen pelvis or they've had a lot of scar tissue in the area, I'm more likely to go to a TVT.

Oh, and one last thing: It's becoming patient choice -- it's always patient choice.

Q. Right.

A. Sometimes we don't use it based on patient choice.

Q. That was going to be a question. You mentioned the difference in your volume of, let's say, using the TVT retropubic or Exact sling a couple years back versus what you're doing more currently now, with it now being more heavily weighted towards the Lap Burch, correct?

A. Yes.

Q. Is that more function of patient choice?

A. It's multifactorial. I try to actually learn from my patients and learn from other individuals. Hence going to Zurich, Switzerland at age 55 to do my -- basically a fourth fellowship.

What am I trying to say? What I'm trying to say is that I learn and I continue to learn by experiencing, by listening to my patients. But one thing I've learned over the last 15 to 20 years of using synthetic mesh is that quite

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often, mesh complications go unnoticed. They're underreported, they're undiagnosed, doctors don't listen to their patients, or they don't understand how to identify the complications associated with mesh. So I personally am more hesitant in utilizing synthetic slings. It's not to say that I don't think they're good -- and I personally am more aware when my patient speaks to me if she has any hesitation at all, whatever the reason may be, then we are more prone to do a Burch.

That being said, it's not that we talk the patients into certain surgeries. In my practice, a woman makes her decision, because in each patient I spend somewhere between an hour to two hours -- I only see four patients a day -- and I try to do the best I can to make them an informed consumer and discuss the medical procedure, the risk, the complications, et cetera.

Q. Okay. You mentioned you see about four patients day?

A. On the average four. Yesterday was three.

Q. How many surgeries do you do a week?

A. On the average Dr. Moore and I coalesce -- it's slower this year because of the way people can't meet their deductibles, deductibles have gone up. So usually we do 400 to 500 surgeries a year. Right now, we're on pace to do probably about 350.

Q. Do you practice evidence-based medicine?

A. I think everybody -- well, do I practice

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evidence-based medicine? I attempt to practice evidence-based medicine, yes.

Q. From your perspective as a scientist and a doctor and a surgeon, what is evidence-based medicine?

A. Well, evidence-based medicine is that you're going to attempt to practice according to the scientific literature based on good, quality science that has been presented in a literature and at meetings that's to the benefit of the patient with the highest cure rates and the lowest complication rates.

Q. Are there certain patient cohorts that you focus on or offer the Laparoscopic Burch procedure to?

A. Repeat the question.

Q. Sure. One of the surgical options you present to your patients is the Laparoscopic Burch, as you've testified.

A. Yes.

Q. Are there certain patient characteristics or cohorts for whom you offer that or is that an across-the-board offering to the patients who you find are suitable candidates for the surgical management of female stress urinary incontinence?

A. The one place I'm extremely -- I offer -- it's an offer to most patients. I get extremely hesitant in what's called a fixed urethra, there's no mobility of the urethra. Some people say they won't use it on repeat surgery. I wrote a paper in 1999 and I proved in my hands, that a repeat Laparoscopic Burch 19.7 months after surgery was 91, 92 percent

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successful. Usually a secondary surgery is not as successful. It's the -- again, it's the art of the surgery. So, for most patients I offer them a Laparoscopic Burch, especially if we're going in laparoscopically already.

Q. Right.

A. We don't have many patients that only get incontinence and that's it.

Q. Right. So if you're going in and you're doing a laparoscopic hysterectomy and the patient needs the stress incontinence procedure, or if you're doing a laparoscopic procedure to treat something that is concerning to you or the patient, would you tend to offer the Laparoscopic Burch as a concomitant procedure?

A. Yes, but there's caveats. One caveat would be, listen, I've already had five surgical procedures for incontinence, I have a fixed urethra. The right operation is probably not going in and doing a Laparoscopic Burch. The risk knowing the spetsaracious with five surgical procedures, an injury to the bowel, the bladder, the operating neurovascular bundle, and blood loss, as well as the attempt at cure is going to be extremely low. I believe she'll have a better success with a retropubic sling, and I will tell her we're going this laparoscopically, with the right operation from my point of view is doing a retropubic sling.

At that point, I'll explain this to her, but

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she still makes the decision.
Q. Okay. You're familiar with the Cochrane Reviews, I take it, on the various conditions for which you provide treatment and care to women?
A. Yes.
Q. In the most recent Cochrane Review I saw on the treatment of stress urinary incontinence, as between the Open Burch and the Laparoscopic Burch, Cochrane reported that there was no significant benefit in efficacy or complications with the laparoscopic approach. Are you familiar with that?
A. I'd have to see the Cochrane Review. I haven't read that one.
Q. Let me ask you this: Do you still do Open Burches or are you -- do you steer away from them for some reason or another?
A. I haven't made an open abdominal incision in 11 years.
Q. Okay.
A. It doesn't mean it can't happen tomorrow.
Q. Right.
A. So the reason why I steer away from it is because I'm in there laparoscopically. Now, if a doctor makes an incision and calls me and says listen, I have a big incision, can you do an Open Burch, yeah, I would do an Open Burch.
Q. But you have a preference of being more minimally

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invasive in your operative technique?
A. Right. The reason -- again, most of our patients are getting full reconstructions; sacrocolpopexies, paravag repairs, hysterectomies. If a woman came in and she only needs a continence procedure, I'd offer her both: Laparoscopic Burch versus a sling.
Q. Have you tracked your outcomes with regard to your efficacy and complication rates with the TVT retropubic and TVT Exact devices?
A. We have not. We haven't gotten around to doing that study, we do so many other studies. So, we have relied on our colleagues, our cohorts, the people that we deal with, the people that I've taught with. I brought TVT to this country in 1998 with Dr. Lucente, Ixodberger, Carl Clukey, Mickey Karram, I went to Sweden to learn it.
Q. Right.
A. And listening to Rezapour and Olf Holmstead, and Christian Falconer, who I trained with at the Carolina Clinic in Uppsala, we brought that procedure back and it stood the test of time and most people did studies and, as you know, it's the most well studied anti-incontinence procedure in the world.
Q. Right.
A. So I personally have not done mine.
Q. Okay. I was just asking because, obviously, I kind of tried to study up on you and I hadn't seen a publication in

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that regard but I didn't want to miss one. If there was one out there, I would be interested to read it.
A. Yeah. There's just so much other stuff to study. That's one I haven't written about yet.
Q. Okay. Have you notice any differences between the TVT retropubic that you began doing -- one of the first surgeons in this country -- and the TVT Exact that you perform now?
A. I think it's an easier delivery of passage of the needle. But I don't consider -- anecdotically, I don't see where the cure rates are any different or the complication rates are any different in our hands. I will tell you that the sling is easier to remove versus the original slings that we used way back in 1998, '99, for whatever the reason may be. It doesn't seem like it ingrains as much.
Q. So it's not the color, it's not the fact that the original TVT you would have been doing back when it first came to this country was just a straight clear as opposed to now there's the blue lines?
A. Correct.
Q. Okay. I know in your report you outline -- page 4 and 5 -- your experience with the TVT-Secur device -- and let me back up.
So you mentioned Vince Lucente. When did you first begin working with him?

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A. Vince?
Q. Yes.
A. I've known Vince since -- I've known Vince since 1994. The Society of Gynecologic Surgery meeting in Nashville, Tennessee at the Grand Ole Opry, we shared a room. We're comrades, we're colleagues, I've operated in his hospital in Lehigh Valley when we was there versus Bethlehem Hospital more than once to show him my style and technique of things.
Q. Okay.
A. We've traveled and taught together, we hunt together, we're friends, but we don't always agree.
Q. Right. So when you're talking about -- obviously you and Dr. Lucente were some of the early surgeons involved in TVT-Secur and its clinical application for the treatment of stress incontinence, true?
A. Yes.
Q. You mentioned that you went to a cadaveric training session in Orlando, Florida with regard to TVT-Secur where Dr. Lucente, I guess, was the lead proctor?
A. Yes. If I remember correctly it was Dr. Lucente and possibly Eimy Sepulveda and, yes, I was -- actually Vince encouraged Gynecare to invite me.
Q. Okay. You stated that -- I'm looking at page 5, just in case you want to follow along, where you're talking about the lack of conformity to dissection technique as discussed

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during a proceeding lecture -- and you stated I recommended putting one's finger into the incision to touch the ischiopubic rami to determine adequate insertion width and depth for mesh placement.

A. Yes.

Q. Can you explain -- explain that recommendation?

A. Yes. Well, this actually occurred -- I can still remember being in the room, far part of the room, right-hand side -- and Dr. Lucente was there and there were two people on one cadaver and I watched them before I walked over to my cadaver, and they were having trouble with insertion of the device and they perforated the urethra and they perforated the vaginal epithelium. And my question was after seeing videos and watching them, that they didn't even know where the anatomy -- you don't know where the implantation of the insertion tip is going. So when I went to my cadaver, it was suggested that, initially, that you make a centimeter incision, and I just watched two people screw up. This is the very beginning. I mean, Vince may have done, I think at that time, maybe 20 cases or so. I said well, the only way to ascertain and to assure ourselves that we're getting into the correct plane is to actually place your finger and then withdraw your finger to make sure that you have adequate dissection to get to the obturator internus muscle.

Q. Okay.

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A. That was the theory and the concept behind it. Thus, reducing the chance of vaginal epithelial perforation, urethral perforation, and tissue dragging.

Q. That would be for the hammock approach?

A. Yes. Yes, it was for the hammock approach. The interesting thing is that when I watch other people in the room -- that's what I do, I watch other people and I formulate opinions -- the average doctor didn't have a clue the difference between the U approach and the hammock approach. They don't have a clue nor did they have -- most people didn't even understand the anatomy because often people being taught didn't have a good fund of knowledge at that point -- at some times.

Q. Let me take a step back. So obviously, you were one of the first surgeons to do the retropubic TVT and you recognized the benefits of that procedure as you used it over the years -- I'm going to chronologically go through the late 90s, 2000s -- correct?

A. Yes.

Q. And then, as you know, Delorme, DeLaval, now comes the transobturator approach. Is that an approach that you used? I know you only tried TVT-O one time, but is that an approach that you used in your practice in the mid- to latter part of the 2000s with any volume?

A. The TVT-O? Is that what you're asking?

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Q. Or the TOT.

A. Yes. I used the TOT, too.

Q. So you prefer the outside-in approach to the inside-out approach?

A. I prefer the outside-in approach based on the fact that I was asked to go to see Delorme when I was in Paris to go to Belgium, I believe is where he was at the time, to watch him do surgery. Vince went, I couldn't make it. I said well, I'll catch you back at the lab in New Jersey. So it was probably 5, I don't know, maybe 8 weeks later I went to the lab -- or maybe 12 weeks later -- and we worked on cadavers and I put the first one in and I told Gynecare to their faces, I will never do your procedure. It's too dangerous. Well, quote unquote, Dr. Lucente doesn't have any problems, he's been doing it. I said that's Vince, but for the average doctor I think it's going to be problematic, and for certain patients it's going to be problematic because you're crossing a mobile joint. Whereas with an outside-in approach, you hug the ischiopubic rami on the distal aspect of the obturator fossa. And in the inside-out approach it's hard to control where that needle exits. So I just couldn't bring myself to actually want to do the surgery. And they were expecting me to be a preceptor, and I said there's no way I can do this and teach people. And they said well, you won't make any money from us, you'll lose all your preceptorships. I said I don't care about money, it's

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about patient care. That's an actual discussion we had in the cadaveric lab.

So later on, Brian Waskom said John, would you at least try one, you know you're capable. I said listen, bring it down, let me look at it, and I did it on one case. The patient did well. Just sometimes you have to go with your gut feeling, and I just said I just don't feel comfortable doing this operation. So that was the last one I ever did. One and only one.

Q. How many outside-in transobturator slings have you placed in your career?

A. Probably well over 150, 200. It would be tough to guesstimate.

Q. Okay. Is that something you do currently, transobturator full-length slings?

A. No. I stopped, I believe, about four years ago.

Q. So then after the transobturator slings, then the Mini-Slings come on the market, correct?

A. 2008, 2000 -- well, this Mini-Sling came out in 2006. The MINI ARC about 2008, I think it was.

Q. All right.

A. 2006 in The States, I should say.

Q. Did you recognize whether or not there was a desire in your field to attempt, through each generation of surgical technique or approach, to move towards more minimally invasive

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technique?
A. Can you repeat the question?
Q. Sure.
A. You mean from me or was the company?
Q. No, no, no. Really, I'm talking about you and your art, your field.
A. Oh, I see.
Q. In your art, in your field, did you -- was there a movement by surgeons in general towards more and more minimally invasive procedures to treat these conditions, such that there was a trans -- a retropubic approach, then it moved to the transobturator, and then it ultimately went to Mini-Slings?
A. I think historically and retrospectively that's pretty self-evident. And, yeah, I think most companies were attempting that with the idea that TVT, transobturator, now single-incision slings, and even at the same -- simultaneously open incisions versus transvaginal and laparoscopic for prolapse and -- yeah, that was the attempt. The balance is success, morbidity, and are they equally effective and less morbid than the predecessor, or are they more effective and less morbid? You can't have same effect -- efficaciousness and have the same morbidity and expect it to be a great operation, because you're not achieving anything other than it's a smaller incision.
Q. Right. Did it make sense to you to go towards a more

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minimally invasive insertion technique by way of Mini-Sling approach based upon your experience and knowledge of your art over two decades?
A. The concept made sense. Thus, the reason that I did 28 TVT-Securs.
Q. Twenty-eight?
A. Yeah. But that was also based on trusting people that I knew, my contemporaries, my colleagues, and some of these people are the leaders in the world that we communicate just -- Michele Cosson, Vince Lucente, Dennis Miller, so these are people that we talk to routinely. And when Vince told me, John, I'm getting great results, I mean, I had nothing else to believe but he was getting great results. And the concept is right; smaller incision, if I can get the same results, what's the downside for the patient? And that was the goal.
Q. Okay. Obviously, by reading your report, you're of the opinion that overall, the TVT-Secur is not as effective as the TVT retropubic device or the TVT-O full-length slings; is that a fair statement?
A. That's an absolutely fair statement, and I think that's proven from day one. Including Dr. Lucente, who does 77 patients, I do 28, we combine our data, he has a 68.5 percent cure rate, I have a 79 percent cure rate at good ol' 6 weeks, which is nothing in the world of surgery. At that point, realizing a TVT is 90 to 95 percent successful at one year and

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I'm getting an 80 percent cure rate at 6 weeks -- that cure rate never gets better, it only goes down -- I had to stop because it wasn't the right thing for my patients. It wasn't beneficial, it wasn't efficacious, and it wasn't the right thing to do. Now, Vince still believed -- and it's his right to believe what he wants and he's a good surgeon -- he told me, he said nope, John, I'm telling you it's a great operation. So he continued down that path.
Q. So you've obviously read studies on the TVT-Secur reporting its clinical effectiveness and safety in women for the treatment of stress incontinence, true?
A. Yes.
Q. And there are studies that report satisfactory efficacy with TVT-Secur, even level one data, correct?
A. Yes, but they're few and far between. There's not a ton of studies that say that the cure rate is over 90 percent. I mean, we can sit there and basically say, study number one, Mauro Cervigni and Bursconi, 24 months out, 89.5 percent cure rate. Okay, that's a decent study. I know Mauro Cervigni, I've operated with him in Rome. I like him, he's a good guy, he's pretty honest. Not a bad study.
Study number 2, we can then look at the Neuman study. I don't know Dr. Neuman from Israel, but he has a 91 percent cure rate at three years out, so those are your two best at this point. Except for Luo, who's from China.

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Now, Luo and his multi-prospective randomized chemical trial of three different studies, he has a 100 percent cure rate, 99.5 percent cure rate, 98.5 percent cure rate. I'm not saying it's not possible, but it gives me a little angst when anybody has a 100 percent cure rate on an operation 12 months out of surgery. I mean, it's a little hard to believe for me. So we still have a couple other studies in the 80 to 90 percent range and that would be -- that I'm aware of and that is Kim from Korea, who sits out at 88 and 89 percent using the UNH technique and then you also have Kandawalla, who has an 84 percent cure rate at 14 months out.
Now, the majority of these studies are still not in the ballpark of the TVT and we're talking about five studies, there may be others. What's important is the longest term studies, Tomaselli at five years out, shows a cure rate of TVT-Secur sitting down the 67 percent range and then Masada study, five years out. Those are the two longest studies that I can remember right now and they're sitting out at 65 percent cure rate. And then when you do the prospective randomized chemical trials, you do the metaanalysis, you do the Cochrane Reviews, you have somebody like Navarre and Steven Jeffries from South Africa looking at all these studies, specifically the randomized chemical trials pulling out the TVT-Securs and saying overall, the mass majority of the highest form of scientific evaluation, that the TVT-Secur is not as effective

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as the TVT-O, inside-out or the TVT -- TOT -- or a TVT-O inside-out, TOT outside-in, and the retropubic slings.

So, again, you're always going to have studies that show great cure rates. What I find hard to believe is that I'm sitting with Vince Lucente, who's the leader in the world, in the world, and his cure rates are 69 percent after 77 patients --

Q. Right.

A. I mean, this is somebody well respected and was the number one leader, the key opinion leader, with maybe the exception of Carl Gustav Nilsson from Finland and Walter Artibani from Verona, Italy, and even those two guys stopped doing the procedure. I've never figured out the reason why, even though they were the first to do the studies in their respective country, because I don't find it in the internal documents, but it sure is crazy -- then we go over to Australia, I know Malcolm Frazer, I know Bruce Farnsworth, I know Marcus Carey, there again Bruce Farnsworth -- I'm sorry, Malcolm Frazer is getting a cure rate of 35 percent. There's a problem with the procedure.

In maybe a few doctor's hands they can get decent surgery, decent cure rates, but for the mass majority based on the literature, based on the internal documentation, based on depositions, based on the prospective randomized chemical trials, based on the metaanalysis, Cochrane Reviews,

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it's not there.

Q. You mentioned a paper by Tomaselli, and I think that's the one you were referencing.

A. Yeah. Wait a second. Is this the 2015 or the 2011?

Q. This is the '15. You mentioned a five-year follow up.

A. Yeah.

Q. So I was just making sure you had that.

A. Yeah. 2015, five-year.

Q. So in this study, this was one where statistically there wasn't a difference in the efficacy between the full-length and the TVT-Secur?

A. You are absolutely right. Statistically, it was not different and I believe it was 65 versus 82, let me just see where it is here. With objective cure rate, 82 versus 68. Absolutely statistical analysis, it is not statistically significant, but he makes sure that he well mentions that it's the downward trend. It's lower-end. What's really amazing, if you look at the long-term follow-up studies, if you hit five years, both of them are in the 60 percent range. Most studies for TVT retropubic, you hit five years, it's 83, 84, 85 and above. So I'm not saying -- and I think even Tomaselli is sort of hitting on here, saying it's not significant but, boy, it's not what we expected. It's a good study.

Q. Yeah. So there are surgeons, though, who got good

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results with TVT-Secur, correct?

A. Yeah. What's interesting --

Q. Is that a yes?

A. Yes.

Q. Okay.

A. What's interesting, though, they're not the surgeons that I would think that would be getting the great results because they're not the true key opinion leaders and the leaders throughout the world. How is it it's fly-by-nights, they wouldn't like that, but they're not the people that led the way or the true pioneers or the true pioneers of minimally invasive surgery and sling surgeries?

Q. Well, you mentioned about this surgeon, Luo, I think in Korea?

A. No. Not Luo, Kim.

Q. Kim, sorry. Oh, Kim.

Dr. Kim who has success rates, I think you mentioned of around 100 percent --

A. No, no. Luo, L-u-o, in China.

Q. Okay. Luo in China. All right. So I was --

A. I don't know if that's how you pronounce it, but it's L-u-o.

Q. You're fine. So Luo, let me rephrase. So you mentioned the surgeon Luo, a surgeon in China who reported very good rates with TVT-Secur, right?

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A. Yeah, that's what he reported.

Q. Have you ever operated with Dr. Luo?

A. No, I have not.

Q. So other than just the fact that his rates are basically almost 100 percent or 100 percent, you don't have any, I would say, personal or first-hand knowledge as to that surgeon producing false data?

A. Absolutely not. And he may truly have a 100 percent cure rate. But it's hard for me to believe that a company like Johnson & Johnson, Gynecare, Ethicon would promote a product that they didn't have any studies before they released it. This stuff came out later and this is a study that's much later than when they released their product, and their key opinion leaders can't get that type of result. I'm not saying Dr. Luo can't get that result, but I'm saying it's the few and far between that can.

Q. Who is the professor in Italy who had good results? Who was the first study that you mentioned?

A. Mauro Cervigni

Q. How do you spell that?

A. C-e-r-v-i-g-n-i, I believe. And actually it was his -- he's the senior author, it's a last name on the list. The first name would be Bersconi, B-e-r-s-c-o-n-i, I believe.

Q. Are they good surgeons according to your knowledge of them or reputation?

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A. I've operated with Mauro, he's a good surgeon. I've actually operated for him in Rome and I've operated with him in Avellino.
Q. And his success rates with Secur you said were around 85 --
A. 89.5 percent at around 24 months, two years.
Q. And that's an acceptable cure rate in your opinion?
A. Yeah. That's a very good -- that's a good, acceptable cure rate.
Q. Is that a peer reviewed or published study?
A. Yes.
Q. Okay. You mentioned Malcolm Frazer in Australia, who reported that he had a high rate of failures with TVT-Secur, correct?
A. Yes.
Q. And he had been doing TVT retropubics before that, correct?
A. According to the internal documents, 6- to 800.
Q. Right. By reputation, have you operated with him?
A. Not with Malcolm Frazer, no. But I know him.
Q. Do you know if he has a good reputation or a reputation as having good hands, being a good surgeon?
A. I understand that he's a good surgeon, yes.
Q. I understand that there's surgeons who have published a lot and write a lot, but they might not have the

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best hands. I'm really interested in is he a surgeon who has good hands, good technique? Is he known for that, to the extent that you know that?
A. To the extent that I know that he's considered to have good hands, I would assume that Gynecare would choose the surgeons that are going to be -- best fit their need and give them the highest cure rate. They're not going to just turn their procedures over to anybody to do, so there's a certain obligation there. I hope that they thought that he was a good surgeon, too.
Q. So as between the success rates by -- I'm going to butcher his name -- Cervigini --
A. Cervigni.
Q. Cervigni, I'm terrible with that. So Cervigini has got roughly 90 percent success at two years, on one hand, good surgeon.
A. Yeah.
Q. Malcolm Frazer has got a 70 or 65 percent failure rate in short-term, good surgeon?
A. Yes. In six weeks.
Q. Obviously, it's not -- and they're both using the same device, correct?
A. From what I understand they are, yes.
Q. All right. So obviously the difference is either one of two things; it's technique and/or patient selection, right?

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A. No. It could also be the device itself. This is the defective design of the device. Listen, Gynecare has a history of producing a good device, i.e., retropubic TVT sling. Essentially, that's what I use today. If they have that history of understanding that device, and even though I don't totally agree with their TVT-O technique, it is proven -- even though I don't agree with it -- it has been proven through the test of time that it has good results, too, equivalent to the TVTs and statistical significance.
Q. Right.
A. They've been able to produce two products for sure that are reproducible products because the design of those products, I don't necessarily would say that they are defective. Now, TVT-O, I think there is a defective design to it, but it still gives you the efficaciousness, not the morbidity side. That being said, they certainly didn't hit the mark with TVT-Secur. This design is defective, it's not -- because the surgeon cannot reproduce the surgical results across the board. You have chosen and, you know, I get accused of this cherry picking I'm sure along the way, but you have cherry picked the top five papers. That's what they are. And I've cherry picked them for you, too, because they are the best results. But there are literally dozens of papers that don't say that it's as effective. And remember, the other thing that you have going on here, you're looking at two-year follow up.

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Q. Right.
A. We saw what happened with Cornu. At 84 percent, 83.5 percent success rate at 6 to 8 weeks after surgery. By 30 months, Cornu is looking at a 60 percent failure. They don't have that problem with TVT and TVT-O.
Q. Right. But the point I'm trying to understand and make -- I'm not cherry picking the data, because I know the data just like you do. There are TVT-Secur studies that show good efficacy?
A. Few and far between.
Q. But there are those studies?
A. Yes, there are. Absolutely.
Q. And there are studies that show efficacy that's not as good in your opinion, correct?
A. Right. And every once in a while a blind squirrel gets a nut.
Q. But -- so one of the things you cited in your report was the Quality Board and Quality Board minutes regarding the Australian -- when the issue arose in Australia you thought Ethicon instituted a Quality Board began analyzing the data to see what's happening here?
A. Yes. Which reference is this?
Q. I don't know the reference off the top of my head, but I saw that you only had one of the Quality Boards, so there were two. And there's something in here I want to ask you

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about. Let's see if I can get to it. Let me ask you this while I'm looking for it: Do you recall in the early year after TVT-Secur IUGA, there was multiple, multiple abstracts published on the Secur device?

A. Fiesta Americana, June 6th, 2007, in Cancun, Mexico. Yes, I was there.

Q. All right.

A. I had a nice chuckle.

Q. I know I saw this earlier.

Did you read the deposition of Aran Maree, the Australian Medical Director?

A. Yes. Well, I assume there's just one deposition. Maybe there's more, I can't remember. I did read one for sure.

Q. Okay. We're on number 7. So this is Miklos 7.

Did you get the defense exhibits that were marked at that deposition? I saw that you had the plaintiff's exhibits?

(Whereupon Exhibit Miklos 7 was marked for identification.)

A. I'm sorry, one more time?

Q. Sure. I saw that you had the plaintiff's exhibits from the deposition of Dr. Maree, did you also see that there were defense exhibits marked? Because I didn't see those on your list.

A. I gotta be honest, I wouldn't know the difference. I

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just know an exhibit as an exhibit. I've seen this before if this is what you're talking about.

Q. Would it have been your pattern of practice to ask for all of the exhibits from that deposition of Dr. Maree or were you just interested in looking at the plaintiff's exhibits?

A. No. I would expect -- I've worked with the BBGA firm before and they are very forward about giving me every aspect of everything. I mean, they want me to see the good and the bad, and they want me to come up with my own opinion.

Q. Okay.

A. And before we ever went down this path, they said what do you think. I said well, I know what my personal experience is, but let me take a look at all the information I can come up with and they give me everything. So, I saw this before this was the --

Q. This was an exhibit in the deposition.

A. It was or it wasn't?

Q. It was.

A. Yeah, because I saw this.

Q. Right. There's other defense exhibits that I haven't seen that you've apparently looked at. The reason I'm asking is because I was the one who was at Dr. Maree's deposition.

A. Oh, really?

Q. Yeah.

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A. Seems like a nice person. No?

Q. No, yeah.

A. Okay.

Q. Nice guy.

So if we turn and we look at some of the early experience, the results from the early experience, is this the Dr. Neuman you were referencing earlier?

A. Yeah. Neuman or Neuman, yes. I believe it to be the same person from Israel. I've seen internal documentation on him, yes.

Q. So this was from 2007. Did you -- were you ever provided this information in the context of your assessment of TVT-Secur back when you were doing it or considering doing it?

A. Not this. But when I was in Mexico, I made sure that I saw all of the TVT-Secur presentations.

Q. Right. It's your understanding that a lot of these are from the IUGA presentations?

A. Not Porta, not Pournaropoulo, not Botha not Alperstein, not Styn, not Spreafico, maybe Neuman was there, I can't remember now. Not Vervest -- no, none of these are that I'm aware of. I'd have to look at the list specifically. If I remember correctly, it would be Karram, Albrick, Saltz, that's three of seven, maybe Meschia -- it's hard. I'd have to look at it. So no, these don't look like they're from Mexico.

What's interesting -- so here we are, we're

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looking at these results and you have some good ones and bad ones, but this is in -- what is this? What date is this, 2007?

Q. 2007.

A. What month? Three months after --

Q. May.

A. So before the IUGA meeting.

Q. Okay.

A. Yeah. So these are very --

Q. Yeah, May 15th. I wouldn't tell you something incorrect.

A. So these are very early results.

Q. Right. And even if we -- so if we look at the numbers on the first page, it's obviously got patients whose success is 85 percent or greater, correct?

A. Yes.

Q. On the second page, you've got patients whose success rates are basically 50 to 77 percent, correct?

A. Yes.

Q. And just numerically, there's obviously more patients who had success rates of 87 percent or higher than those whose success was lower than 87 percent?

A. Yes.

Q. By a factor of about 5 to 1, right?

A. Yeah. The problem is, once again, nobody's given me the mien follow-up here. With my assumption based on the

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product release in 2006, this can't be over a year data.
Q. Right.
A. As you already know from other people's studies, success rates with this product go dramatically down. Even as high as 95 percent to 40 percent within two-and-a-half years.
Q. What -- from a complication perspective, did you find any benefit to TVT-Secur in reducing, you know, postoperative pain or any other complication risk that you observed?
A. That I observed with my surgery or --
Q. With your surgery first, and then in your analysis.
A. It is difficult for me to remember 28 patients from back in 2006, exactly the situation. The thing that I do remember was there was a fair amount of bleeding because of the razor blade device. Number two, the high failure rate. High failure rate means that that patient is subjected to another potential surgery if she agrees to it at a higher rate than the average person with a TVT or TOT. Number three, is that I do believe there was less pain for the surgery versus a TVT or a TOT or TVT-O, there's obviously less leg pain. I don't remember what my extrusion rate was back then, for some reason it's not documented -- then again it was only a six-week follow up. The only thing we were interested in was primary objective outcome, which was stress incontinence. So that was my experience. When I look at the literature, and if we work our way from retrospectively -- no, let's work our way

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prospectively -- without looking at the randomized clinical trials yet, we know that even Piet Hinoul, when he wrote his paper, when Piet Hinoul in 2010 wrote his paper on a prospective randomized chemical trial with Vervest, with Milani, and Jean-Paul Roupher from the Netherlands, and they came right out and said listen, it's not as effective as we thought. It's not as good as TVT-O. And on top of that, we have an injury -- we have a mesh exposure rate of about 7 percent. We have Hoda in 2012 with Rosenbaugh with an exposure rate of 19 percent. We have Masada with an exposure rate of 7.3 percent. We also have Rousey, who was with Michele Cosson, and Michele Cosson was one of the biggest players in the world for Gynecare with their TVM at the time -- a couple years later, a year later, they were already producing it and their erosion rate was 14 percent. Then you look retrospectively and you look at the Cochrane Review and what we see is when you compare the TVT-Secur to TVT-O or TOT or retropubic sling, there's a higher rate of vaginal mesh extrusion, a higher rate of bleeding, a higher rate of urethral and bladder perforation, and a lower rate of pain.
Q. You said extrusion, bleeding, what was the third one? Oh, urethral perf --
A. Urethral and bladder damage.
You know, it's funny when you look at, I think it's Hoda's study, she talks about perf, but she also talks

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about erosion into. Sometimes that's very difficult to determine whether somebody perfs it or they eroded into the urethral bladder.
Q. Do you do any autologous pubovaginal slings either harvested from the rectus fascia or the fascia lata?
A. Yes.
Q. You currently do those?
A. I do them if it's warranted, yes. It's rare.
Q. Is that because of their higher morbidity or voiding dysfunction or both?
A. I've not seen it to be as problematic with voiding dysfunction. I stopped doing fascia lata -- tensor fascia lata slings because the increase rate of about 8 to 10 percent herniation of the quadricep muscle through the lateral aspect of the thigh. So on rare occasion, we do harvest from both. It is a -- one of the problems is even though cure rates are considered just as efficacious, if there is a problem, they're harder to remove, they're harder to adjust, and some patients just eat up the material. They make an enzyme that can actually destroy their own tissue that doesn't have a good blood supply because you've harvested and retransplanted it. We just don't find that they work as well, at least not in my hands.
Q. Right. When you say -- so for mesh extrusion, mesh exposure, you're talking about the visibility of the mesh in

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the vagina, not an erosion into the bladder or urethra?
A. Yes. That's all I --
Q. Just so you and I are on the same page and I know what you're talking about.
What data shows the statistically significant increased risk of mesh extrusion exposure with Secur compared to the other stuff?
A. The Piet Hinoul and the Masada study.
Q. The Piet Hinoul study, the data was not statistically significant, I'll represent that to you. I'll ask you to assume that is true.
A. Okay.
Q. All right. That's more hypothetical, we'll set that one to the side. What's the other study you said?
A. Masada.
Q. Masada. Masada was the metaanalysis, correct? Or am I thinking about -- are we talking about different studies?
A. Wait a second. No. It's the -- I'm sorry, wait a second. Just let me think for a second. Repeat your question.
Q. Sure. The Masada study you referenced, what is that study?
A. Let's back up for a second. What was the original question? We were talking about --
Q. Mesh exposure, extrusion, and which data, if any, show a statistically significant increased risk with TVT-Secur?

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A. That was the Masada, I believe.
Q. Do you know offhand, was that an individual study or a systematic review or --
A. Gosh, I believe it was a systematic review. We can look it up, though. Do you have a copy here?
Q. I don't think I have the Masada to be honest with you. I don't want to get you bogged down because I only have limited time.
A. Okay.
Q. But if Masada is the one you're relying on, that's fine. I'll go figure it out. I'll find it.
A. Also looking at the Cochrane Review by Steven Jeffries and his team where basically they say at the end there's an increased rate of --
Q. Did you look to see whether that was statistically significant?
A. No.
Q. And numerically how much of a different rate?
A. Yeah, that's one of the problems. The incidents of these complications are so low and most studies actually didn't look at the difference and one of the down sides of this study, and this is from years of experience looking at the erosion rate --
Q. Right.
A. -- is the erosion rate, from my perspective, my

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experience, my knowledge, my expertise in taking out over 800 to 1,000 pieces of mesh, is that it goes undiagnosed. Because even if you look at Piet Hinoul's study, they talk about adverse events. But in the primary, secondary endpoint, it doesn't say we're going to look for mesh extrusion, it doesn't say that. You gotta delineate, not just an adverse event. So often when people are getting examined -- a lot of these times when you're examining a patient, it's not just visualization, it's palpation.
Q. Right.
A. Because of the ruga of the vagina, the waves, a lot of times you don't see it. Every patient that I took out who had mesh extrusion, had a previous surgeon that told them there's nothing wrong with you. So it is dramatically and drastically underreported.
Q. Was that number 7, Doc?
A. Yes, it is.
Q. You would agree that there are numerous studies including high level randomized control trials that do not show a statistically significant increased risk of mesh extrusion or exposure with the TVT-Secur, correct?
A. Yes, I do agree. But also, I want to state that most studies actually didn't clarify to the primary, secondary endpoint in their study. It's an incidental finding. And number 2, it goes undiagnosed over and over again. I know that

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personally from my practice and having the largest paper in the world on removing mesh.
Q. So this is a paper I assume you're familiar with. This is the SGS, who did their systematic review and metaanalysis on the various surgical options to treat incontinence. Are you familiar with this paper?
A. It's been a while since I've read this.
Q. I just have a couple questions. Let's -- do you put more weight into systematic reviews and metaanalysis than an individual RCT? I'll ask you -- this is where I'm going --
A. Yeah.
Q. I'm sure you've heard Doctors of the Oxford Levels Evidence Pyramid.
A. Yes.
Q. Something you were probably taught in -- actually I saw you did an undergrad in the sciences so you probably knew about this even in your college sciences.
A. Probably not.
Q. Okay. What number are we up to?
A. This is 8.
Q. Okay. So this is the Oxford Levels of Evidence and you see at the top they have systematic reviews. Metaanalysis has a higher quality of evidence before individual RCTs and things of that nature.
(Whereupon Exhibit Miklos 8 was marked for

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identification.)
A. Yes.
Q. Is that something you agree or disagree with?
A. Generally, I agree with it.
Q. Okay.
A. I mean, I'm sure there's always exceptions to the rules and you have to take in your own personal experiences and your own education and knowledge but, generally, I agree with it. Generally.
Q. Yeah. For the application -- that's not the right word. Obviously, you're always going to bring into bear your personal experience, knowledge, and training, correct?
A. Yeah. It's a little more complicated than that, though, sometimes. You can tell me laparoscopic sacrocolpopexies are not efficient, but you haven't been in my OR. And that's not being arrogant, it's being honest. And people will look at me, and they'll say, just like the Neuman study or something, well, your cure rates are a little higher than most or your experience, you have less complications so I can't fully -- but this is the general, I would say, with the quality of evidence, I agree the metaanalysis sits at the top.
Q. Individual opinion is anecdotal according to the levels of evidence, true?
A. Yes.
Q. If you look at Table 1, it's got all the different

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RCTs included in this systematic review, and then if you go to the last page of the table, just where they get to Mini-Slings, do you see that?
A. Yeah, let me just clarify that statement; an individual's opinion is anecdotical. No, wrong. It all depends on the amount of experience, knowledge, and expertise. Perhaps you're the only person in the world who has any experience, knowledge, and expertise in a certain subject. So my opinion is based on information of years, and sometimes it's not just anecdotical. It holds a lot of weight. And that's why companies like Gynecare, Barb, will pull us in to act as consultants. There's no metaanalysis. That's all I'm saying. I just don't want to put myself in a corner.
Q. Yeah, I gotcha. But for the scientific projection of population-based treatment, what you can expect from surgeries, systematic reviews and metaanalysis are at the top of the pyramid --
A. Yes.
Q. -- because those are the ones you can most reliably project out into a large population?
A. Yes.
Q. As opposed to, even great surgeons like yourself, your own cohort series or personal experience with a technique is deemed anecdotal for the projection out onto the masses because they're not John Miklos.

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A. Okay. I agree with that, yes.
Q. That's what I was getting at.
A. We're on the same page.
Q. So at the last part of Table 1, it's got all the Mini-Slings --
A. This is --
Q. Yep. We're on the same page.
A. Okay.
Q. Andrada is the first one I show.
A. Yes.
Q. And you see, it looks like virtually every Mini-Sling study that made the criteria for the systematic review included the TVT-Secur except for Oliveira, that used MINI ARC, correct?
A. So the comparison is Secur versus the TVT-O most of the time, yes.
Q. Yeah. And it's in every study except for Oliveira, which used the MINI ARC?
A. Yes.
Q. And of all the Mini-Slings, I think we can agree that TVT-Secur has been studied the most, correct?
A. Yes.
Q. So the rates of adverse events if you look at Table 3 --
A. Okay.
Q. Exposure has got Mini-Slings at two percent -- just

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that way we can look at it together.
A. Oh, I'm sorry.
Q. Did I look at the wrong one?
A. Yes.
Q. Actually, I remember you mentioned Hoda, Hinoul's papers --
A. Yes.
Q. -- a bunch of papers on TVT-Secur with regard to exposures.
A. Yes.
Q. This metaanalysis takes into account those studies, correct?
A. Hoda -- yes.
Q. So the rate of exposure of two percent with the Mini-Sling for which TVT-Secur is representative of every study except for one, do you believe that that's an accurate rate?
A. I believe that's what they calculated here and, yeah, that's what they calculated is that the Mini-Sling is responsible for two percent.
Q. Is that consistent or inconsistent with your overall review of the literature?
A. It's very difficult to say because when you -- again, when I talk about this and we review various papers, they don't even mention mesh extrusion. Again, it wasn't a point, a primary endpoint or a secondary endpoint in most papers. There

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are some that are higher, there are some that are zero, so it's across the board. So I would look at this metaanalysis and say, yeah, two percent is probably right based on what they've told me here. The problem is you're talking about one complication in a product that is not efficacious.
Listen, if I have a sling and the cure rate is 5 percent and I have zero erosion rate, what good is the sling? You have a procedure here that has a cure rate at 3 and 4 years out and 5 years out of less than 68 percent, 65 percent, 55 percent. Versus 5 years out going at 90 percent for other slings. Not only do you have a failure in a lack of efficacy, but that lack of efficacy pushes these patients back into the operating room. So you can tell me that the erosion rate is similar, that's nice. But why even go to the operating room in the first place? Get the right sling. Get the TVT, don't waste your time on this. I'm happy the erosion rate is roughly the same, but I still wouldn't want the operation. And most patients wouldn't if they were given the choice.
MR. MATTHEWS: Don't pause too long or I may go to the bathroom.
MR. SNELL: If you need to, we can take a quick break.
(Whereupon a brief break was taken.)
Q. (By Mr. Snell) Just so I understand where you're coming from in your opinion that TVT-Secur is defective, we can

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agree obviously that it wasn't defective in some surgeons hands, true?

A. No. I won't agree to that. Defective design entails that you're not going to get -- defective design to me means that your risk outweighs the benefit with the product that's in your hands. I personally used it on a cadaver and on the first cadaver I used it on, I knew it was defective. Number 1, the razor blade, exactly what it is, the insertion tip, is unprecedented. I have been around in courses, in operating rooms, and have used all other types -- many other types -- of TVTs, TOTs,TVT-Os and they're all the same. They're long, narrow tubes that are cylindrical, cylindrical with a conical tip usually. Now all of a sudden, you have a new device that has a razor blade on it and you're asked to make a 1 centimeter incision and you're delivered this razor blade device that cuts through tissue, including urethra potentially, bladder potentially, and periurethral tissue.

Not only is it unprecedented and it destroys tissue and increases -- we know with that type of trauma it's going to increase scar tissue. Now, the actual release of the device, the releasing mechanism was horrendous and this is documented in the internal documents. It was said that day in the operating room on the cadaver. Vince Lucente agreed with me. He said, yeah, they need to redo it, but there's secrets of doing it. You gotta jiggle it. If you jiggle it -- and we

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see this even -- Hinoul even says it. Hinoul was their employee and he's writing this stuff in his paper. He's saying well, yeah, it could dislodge. Yeah, you jiggle it, you're dislodging the insertion tip.

Q. Right.

A. That's the next problem, the insertion tip has never been proven. Then you have this polysorb which is vicryl -- is poly-p-dioxanone, basically it's an absorbable material that has never been utilized before in the pelvic floor.

And finally, the device itself, when you get that device it was unlike any other device. When you got a TVT, they gave you everything you needed almost. Everything that you can use to apply the mesh. This, you actually had to attach a straight hemostat to it or a needle driver.

Q. Needle driver.

A. Which was ridiculous because people were actually -- you can't control the trajectory of where this needle tip is going and then trying to get the release and insert and stay. And then the last thing is because you're pushing it in, you're not pulling it through like the TVT or TOT or the Abbrevo, you have difficulty adjusting the tension because you're just pushing. How tight is tight? So it's a completely defective design.

Q. So it's your opinion that it's defective because of those attributes, but we can agree that even with those

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attributes to which you find objectionable or defective, surgeons still can get good results with TVT-Secur as evidenced by peer reviewed public literature you are aware of, correct?

A. Absolutely. You can kill a rabbit with a stone, too, but not too many people can do it.

I mean, the bottom line is when you produce a product, you need a product that is reproducible -- gives you reproducible efficacious results with minimal morbidity that you can put in your surgeons' hands. Here we see a product that was not -- they couldn't reproduce the results. So there's some people that can do it, but this is not to the benefit of the patient. If we go and look at J & J's credo, which I haven't looked at in a while, patient care and the responsibility to the patient is first and foremost. This is -- I've got to be honest with you, honestly, if this is your mom, you wouldn't give her a TVT-Secur. You would not.

Q. So you're aware that they received complaints from some surgeons on Secur and they did various investigations and did -- came out with key technical points on TVT-Secur?

A. Yes. They received some complaints from some surgeons, yes.

Q. I mean it's in the Quality Board minutes that you've looked at and that I've looked at, correct?

A. The problem is -- here's what's amazing to me: I never knew -- I was a leader for TVT, I never knew there was a

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place I could complain to in the United States. I used TVT-Secur, nobody ever took my complaints. So why is it that only some people got to complain and I never got to complain?

Q. Are you telling me you weren't aware that you could make complaints to Ethicon or the FDA under the Maude Database for untoward outcomes you deemed to be potentially from a device?

A. I did not know, and I was a preceptor for Gynecare, that you could actually make a complaint -- I mean, I knew I could complain to the rep or the next time I saw him at a meeting, but I didn't know that you actually wrote it out and logged it out. I swear to God, I didn't know. It blows my mind because if I'm a leader in their field at the time TVT and potentially TVT-Secur -- if I would have liked the product, if I would have believed in it and I had good success, I would have been a preceptor for it. I never knew that I could complain. I just quit -- stopped using it at that point.

Q. You saw that they came out with these key technical points to try to make sure surgeons were using the correct pathways, using the correct insertion techniques, dealing with fixation and proper removal --

A. Yeah, I've seen this --

Q. -- without having the device back back out on you?

A. Yeah. I never understood when this was produced because I never saw a copy of this, so --

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Q. This was produced in 2007. You're familiar with the TVT-Secur DVD-ROMs that used to be out?
A. Yes.
Q. It starts with the presentation of the hand and there's a Secur in it and there's the IFU, hammock video, U video. There's various different files and animations that one could see and this was one of the files for both the U and the hammock approach. I'll represent to you, this was in the DVD I pulled down the other night from May 2007.
A. Okay.
Q. Honest.
A. I believe you.
Q. It was cleared and approved by, internally, in I think March -- late March of 2007. That's another representation I'll make to you.
A. Okay.
MR. MATTHEWS: By Ethicon?
MR. SNELL: By Ethicon, exactly. A copy review is what that --
MR. MATTHEWS: When you start throwing words around like cleared and approved --
MR. SNELL: Right.
MR. MATTHEWS: -- you know my antenna goes up.
MR. SNELL: That's fine.
A. What I don't understand --

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Q. (By Mr. Snell) Well, my question is, have you reviewed this document forming your opinions?
A. No, I haven't. If I have, I don't recall it, and I started reviewing the documents back in October, a lot of this stuff. So, is there a specific area? I just don't remember this specifically.
Q. Okay. I was going to ask you about it if you had reviewed it but if you haven't, then I'm not going to waste your time because we've only got a couple more minutes.
A. Okay.
Q. How about this: Hypothetically, if Ethicon put this out to surgeons, key technical points trying to help them understand proper placement, fixation, you know, withdrawal of the device so it doesn't back out and get loose, was that something you would approve of as being a good step towards mitigating a problem that they've seen?
A. I think it's the first step. But if this was so darn important, why didn't they change your IFU? You have Dave Robbins saying the most important part of this surgical technique is that everybody should adhere to the IFU. He makes that statement in the internal documents. And then you have Ramy Mahmoud who sits there and says, who's the ex-CMO of Ethicon, he's sitting there saying the same thing, the training is so important. And Mark Gill saying the same thing, that we're having problems with our training. If it were so

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important, they should have retrained everybody. But we saw that they didn't retrain people because there was cost constraints.
If they really believed in patient care, and if they really believed in the quality of surgery for the patient -- I still can't get why Vince Lucente, here's your leader in the world and he can't get these great cure rates. And he came up with all different ideas. Where's his malleable device? I remember him talking to me about this at the SGS meeting, he goes well you gotta put a malleable. I said where's this in IFU? Where's the literature -- where is it from the company saying we should use the malleable device? Well, it's my trick and technique. If it was so important, then why wasn't it general common knowledge.
Listen, when there's a bad drug on the market, I get a letter in the mail. I don't even use these drugs and I get letters in the mail. I never remember getting anything that told me how from a mailer and I saw nothing in internal review because I was very interested, did Gynecare ever send out to their surgeons or all surgeons this change of technique.
Q. So based on the investigation you did -- I want to make sure I understand this. It's your understanding that Ethicon did not invest in retraining surgeons after these issues arose with regard to TVT and its efficacy or the device backing out?

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A. There were minor issues where they would -- they sent to the engineer like -- I mean if it was a major issue, they wanted to send Dan Smith, the engineer that actually produced TVT-Secur, they sent him to Germany to train the doctors, which is sort of inappropriate. You're an engineer, you don't really do the surgery on live patients, and you better not be. Then they offered to send him to Australia, which was nice of them, but by then they'd already taken it off of the regulatory list, they put a block on it. So I don't ever remember anybody ever coming back to me and saying hey, let's retrain you and let's show you how it's done. One cadaver lab and boom, you're on your way. I never even got to go to somebody's operating room.
Q. Did anyone ever turn you down for training at Ethicon or did you ask for training and they wouldn't allow you to do it?
A. No, because I didn't know at the time that this existed.
Q. Oh, no. I'm saying was there ever an occasion where you wanted to be retrained on something and you expressed that to someone at Ethicon and they said no?
A. No, because that's the 28 cases -- when I get an 80 percent cure rate, and Vince, the leader in the world, gets a 69 percent, I can't possibly believe that you guys -- he's the leader, he's the man. He taught Australia. I mean, the only person above him would have been Carl Gustav from Finland and

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maybe Artibani from Verona, Italy. That would have been it. And if he can't get it down right, why should I even -- let me go back to what's true and tried. At that point, ten years of TVT that was known to be effective and safe in most doctor's hands.

Q. You mentioned urethral and bladder perforation with TVT-Secur. Are there any studies or data that you're aware of that show a statistically significant increased risk of those complications with Secur?

A. Maybe I misunderstood when I read but, again, it would have been the Masada study.

Q. Okay.

A. Again, mostly it was the prospect of the metaanalysis done by Jeffries that says there's increased risk.

Q. Okay. You are aware that there are level 1 studies that don't show a significant increased risk for TVT-Secur on those complications?

A. Absolutely.

Q. Have you done an evaluation to see whether the majority of studies show no difference or the majority of studies do show a significant difference?

MR. MATTHEWS: Which complications?

MR. SNELL: The urethral and bladder perforation injury.

A. The problem with doing a study of this nature is it's

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almost impossible because overall, the injury rates are so low.

Q. (By Mr. Snell) Right.

A. But what they were able to do was do comparison against TVT-O and say there's a preponderance of the evidence that shows there's a greater risk with TVT-Secur of injuring the urethra and the bladder, but I doubt there was the power analysis there.

Q. Okay. Do you rely on statistical significance to inform you on what are real scientific findings as opposed to something that may be a trend or hypothesis generated?

A. I use statistical significance, I use biostatistics, I use my expertise, my knowledge, my own training, and my own awareness of what I've been exposed to in this world. And I also taught the individuals who have more experience than myself, so it's a combination of a lot of things. But I certainly use statistics, too.

Q. Does TVT-Secur, in your opinion, have a significantly higher risk of urinary retention? And if so, what's the data that supports that?

A. No. I don't believe it has a higher rate of urethral obstruction and high urinary retention.

Q. You mentioned because of the cutting blade, and the fact that you're going to have a little more scar tissue than the scar tissue that will be formed with TVT, correct?

A. Yes.

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Q. So that scar tissue that would form after the TVT-Secur, has that translated into a complication that has been reflected in the reliable scientific literature to be higher than whatever comparative you want to compare it to?

A. Well, the problem is we can't -- here's what we do know: If you create more trauma, you have increased inflammation. Increased inflammation can actually cause problems with the lodging of the mesh. So, therefore, you're reducing the chance of cure rates. Reducing the chance of cure rate, you're predisposing this individual to an increased chance of another surgical procedure. I think I did mention about the device, too, that nobody has ever tested at that point an 8 centimeter piece of mesh going from sidewall to sidewall into a point of lodging or stabilization with polysorb. So that in and of itself has never been studied.

Q. Did you have a problem, though, with MINI ARC that went 8.5 centimeters and lodged into the muscle with the barb?

A. No, but I do believe that MINI ARC can potentially have its problems, too. That's why we continue to investigate. I've taken out a fair number of MINI ARC for pain, too.

Q. I know you were involved in one of the early cohort studies on MINI ARC, you and Dr. Moore published in 2008 or 2009 --

A. Yes. Our primary endpoint was -- this is the way most studies are -- when you first start off with a new study,

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we sort of gloss over complications unless they're intraoperatively because you don't have the time to explore it yet. The primary endpoint is usually intraoperative complications, blood loss, damage, and then objective or subjective cure rate 6 weeks, 6 months, a year out. Hopefully a year out.

Q. Right.

A. So I think the problem with a lot of these complications -- I've had women that were my patients with certain types of products that are coming back 5 and 6 years later with complications of pain.

Q. You've seen in some of the reliable randomized trials that MINI ARC is not as effective as the TVT or the TVT-O?

A. Yes, but most of them don't have any long-term follow up.

Q. Right. Any other complication you believe has a statistically significant increase risk or rate for TVT-Secur other than the ones we've talked about? I've got a list, you know, fistulas, de novo urge, but if there's none that you're aware of, then I don't need to waste time.

A. Not other than what's on my list.

THE WITNESS: It's 12:25.

MR. SNELL: I know you've got to roll. All right. Thank you.

(Deposition concluded at 12:25 p.m.)

(Pursuant to Rule 30(e) of the Federal Rules Of Civil Procedure and/or O.C.G.A. 9-11-30(e), Signature of the witness has been reserved.)

STATE OF GEORGIA:
COUNTY OF GWINNETT:

I hereby certify that the foregoing transcript was reported, as stated in the caption, and the questions and answers thereto were reduced to typewriting under my direction; that the foregoing pages represent a true, complete and correct transcript of the evidence given upon said hearing, and I further certify that I am not of kin or counsel to the parties in the case; am not in the employ of counsel for any of said parties; nor am I in any way interested in the result of said case.

____
Heather Brown, RPR
CCR 4756-4284-5258-1376

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ACKNOWLEDGMENT OF DEPONENT

I,____________________, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____

JOHN R. MIKLOS, MD DATE

Subscribed and sworn
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My commission expires:______________

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Notary Public

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